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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	Miller et al.	
Serial No.:	09/258,947	Examiner: G. Ewoldt
Filed:	March 1, 1999	Art Unit: 1644
For:	MIMOTOPES AND ANTI-MIMOTOPES OF HUMAN PLATELET GLYCOPROTEIN IB/IX	

CORRECTED APPEAL BRIEF

Assistant Commissioner for Patents
Washington, D.C. 20231
MS AF

Sir:

In response to the communication dated January 16, 2004, applicants hereby submit the corrected appeal brief in triplicate for the above-identified patent application.

I. Real Party In Interest

The real party in interest is the assignee The Research Foundation of State University of New York. The assignment was recorded at reel/frame 009988/0717 on June 1, 1999.

II. Related Appeals And Interferences

There are currently no other appeals or interferences known to appellant, the applicant's undersigned attorney or assignee which will directly affect or be directly affected by the decision in the pending appeal.

III. Status Of Claims

Claims 9 and 11 are pending. Claims 1-8 and 10 are canceled. Claims 9 and 11 stand rejected under 35 U.S.C. § 112 (first paragraph) for lack of written description and lack

of enablement. Claim 11 stands rejected under 35 U.S.C. § 112 (second paragraph) for indefiniteness.

IV. Status Of Amendments

An amendment to claim 11 was filed subsequent to final rejection (on October 27, 2003). As set out in the communication dated January 16, 2004, the amendment was not entered. A Supplemental Amendment Under 37 CFR 1.116 was submitted via facsimile to the U.S. Patent and Trademark Office on February 12, 2004. The status of that amendment is unknown. Claim 11 as set out in the appendix does not reflect the change made in the amendment.

V. Summary of the Invention

The present invention relates to an isolated peptide of 5 to 20 or 20 to 40 amino acids residues (Specification page 14, lines 7-16) in length capable of binding to a second peptide having an amino acid sequence as shown in SEQ ID NO:174 (Specification page 22, lines 3-6), where the isolated peptide inhibits ristocetin induced aggregation of platelets, and wherein the isolated peptide has a three dimensional structure complementary to the three dimensional structure of the second peptide (Specification page 22, lines 6-12).

In addition, the present invention relates to an isolated peptide of 5 to 20 or 20 to 40 amino acid residues in length which inhibits ristocetin induced aggregation of platelets, the isolated peptide being identified by selecting a library of test peptides, each test peptide being of 5 to 20 or 20 to 40 amino acid residues in length; exposing the library of test peptides to a sample peptide consisting of an amino acid sequence as shown in SEQ ID NO:174; selecting test peptides from the library that binds to the sample peptide;_screening the selected test peptides for ability to inhibit ristocetin induced aggregation of platelets; and

identifying the screened test peptides that inhibit ristocetin induced aggregation of platelets to isolate the peptide of 5 to 20 or 20 to 40 amino acid residues in length which inhibits ristocetin induced aggregation of platelets (Specification page 24, line 33 to page 25, line 7).

VI. Issues

(1) Whether claims 9 and 11 are properly rejected under 35 U.S.C. § 112 (first paragraph) for lack of written description where the specification as filed has a proper written description.

(2) Whether claims 9 and 11 are properly rejected under 35 U.S.C. § 112 (first paragraph) for lack enablement where the claims are enabled by the specification as filed.

(3) Whether claim 11 is properly rejected under 35 U.S.C. § 112 (second paragraph) for indefiniteness where the claim, as written, is definite.

VII. Grouping of Claims

Claims 9 and 11 stand or fall together.

VIII. Argument

A. Issue 1: Whether claims 9 and 11 are properly rejected under 35 U.S.C. § 112 (first paragraph) for lack of written description where the specification as filed has a proper written description.

The specification as filed satisfies the written description requirement for the claims. In particular, page 22, lines 3-12 fully describes an isolated molecule capable of binding to an isolated peptide which comprises an amino acid

sequence as shown in SEQ ID No:174. Further, the specification on page 22, lines 6-11 indicates that the isolated molecule inhibits ristocetin induced aggregation of platelets and has a three dimensional structure complementary to the three dimensional structure of the isolated peptide. Peptides of from 5 to 20 or 20-40 amino acids in length are described on page 14, lines 7-16. Further, a large number of species are listed that define the claimed genus (see specification, page 17, line 23-page 18, line 15). Each of the listed species of peptides is defined as meeting the limitations of the claims. Claim 11 is fully described on page 24, line 33-page 25, line 18.

Firstly, it is the position of the U.S. Patent & Trademark Office ("PTO") that the specification discloses properties which the peptide of the claims should have and that no actual peptides comprising the properties are disclosed (office action dated March 20, 2003, paragraph 4). Applicants respectfully disagree. The specification, as described above, lists numerous species of peptides on page 17, line 23-page 18, line 15 which are capable of binding to the first peptide (page 17, lines 3-5). Further, it is the PTO's position that none of the peptides have been shown to include the recited three dimensional structure and that none of the claimed peptides have been described by structure and function. Applicants submit that the PTO is employing the improper standard in determining whether the application as filed complies the written description requirement of 35 USC § 112(first paragraph).

To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the invention at the time the application was filed (Guidelines for the Examination of Patent Applications Under 35 USC 112, P1,

Written Description Requirement, 66 Fed. Reg. 1099 (Jan. 5, 2001)("Written Description Guidelines"). Possession may be shown in a variety of ways including a description of distinguishing identifying characteristics sufficient to show that the applicant was in possession of the invention (Written Description Guidelines at 1104). An actual reduction to practice is not required (Id.). Further, there is no requirement that the features of the invention must be defined by structure and function (Id.). As detailed above, the claimed invention was described in sufficient detail to meet the written description requirement. Further, the limitations of claim 9 to which the PTO objects are contained in claim 9 as filed. There is a strong presumption that an adequate written description of the claimed invention is present when the application is filed (Written Description Guidelines at 1105). Rejection of an original claim is meant to be a rare occurrence (Id.)

With particular respect to a claim drawn to a genus, the written description requirement for a claimed genus may be satisfied through description of a representative number of species which have a combination of such identifying characteristics sufficient to show the applicant was in possession of the claimed genus (Written Description Guidelines at 1106). There may be situations where one species is a "representative number of species" (Id.). Satisfactory disclosure depends on whether one of ordinary skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed (Id.). In the present patent application, as filed, the claimed invention is described in sufficient detail to allow one of ordinary skill in the art to recognize that applicants had possession of the claimed invention having the distinguishing characteristics of (1)

being of 5 to 20 or 20 to 40 amino acid residues in length, (2) capable of binding to SEQ. ID. NO: 174, (3) inhibiting ristocetin induced aggregation of platelets and (4) having a three dimensional structure complementary to the three dimensional structure of the second peptide. Each of the numerous species listed on page 17, line 23 to page 18, line 15 is described as having these distinguishing features. Accordingly, the rejection of claims 9 and 11 for lack of written description is improper and should be withdrawn.

B. Issue 2: whether claims 9 and 11 are properly rejected under 35 U.S.C. § 112 (first paragraph) for lack enablement where the claims are enabled by the specification as filed.

The present application, as filed, adequately describes how to make and use the present invention. In particular, the specification describes a method for making and using the claimed invention that bears a reasonable correlation to the entire scope of the claims without requiring undue experimentation. Experimentation is permissible, if routine or if the specification provides a reasonable amount of guidance (Manual of Patent Examining Procedure ("MPEP") 2164.05). Accordingly, one of ordinary skill in the art, based on the information contained in the specification, as filed, describing identifying anti-mimotope peptides (page 17, lines 9-22; page 27, line 5 to page 32, line 23) and based on the skill of the art in methodology for identifying anti-mimotope peptides that bind to particular mimotope peptides (as disclosed in references cited in the specification and in the amendment dated February 8, 2002 [1]),

[1]These references were known and available to the public prior to the filing date of the subject application, and include:
Balass, M. et al., Proc Natl Acad Sci USA 90:10638-10642 (November 1993);

could make and use the claimed invention. Accordingly, applicants contend that the identification of peptides that bind to the specifically enumerated mimotope sequence (SEQ ID NO:174) is enabled to one skilled in the art in view of the disclosure in the specification and the state of the art as of the filing date of the subject application.

In particular, the specification, as filed, identifies numerous anti-mimotope sequences (for example, page 17, line 22 to page 23, line 15) which bind to the isolated peptide (the mimotope). An example of the methodology of identifying peptides which bind to the mimotope sequence is provided at page 29, line 33 et seq. A description of the synthesis of a peptide is shown at page 39, line 6 et seq. Furthermore, the claims, in addition to being limited in regard to the particular mimotope sequence, are also limited to those peptides that inhibit ristocetin induced aggregation of platelets. The identification of such peptides which have this desired functional property can be routinely done using, for example, the methodology disclosed in the specification at page 38, line 13 through page 40, line 20.

Lastly, the PTO, in the outstanding office action, indicates that the specification appears to disclose a method that is enabling for producing a peptide which meets the limitations of the claim (Outstanding office action, paragraph 5). Applicants assert, therefore, that the claims to the peptides are, therefore, enabled, because the specification teaches how to make and use them. Firstly, Applicants

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Christian, R.B. et al., J Mol Biol 227:711-718 (1992);
Cwirla, S.E. et al., Proc Natl Acad Sci USA 87:6378-6382 (August 1990);
Hobart, M.J. et al., Proc R Soc London B 252:157-162 (1993);
LaRocca, D. et al., Hybridoma 11:191-201 (1992);
Scott, J.K., Trends in Biochem Sci 17:241-245 (1992);
Scott, J.K. and Smith, G.P., Science 249:386-390 (July 27, 1990); and
Smith, G.P. and Scott, J.K., Methods in Enzymology 217:228-257 (1993).

Copies of each of these references were provided to the Examiner with applicants' information disclosure statement.

disagree with the PTO's assertion that the peptides themselves have not been shown to exist, because, as set forth in detail above, the peptides have been fully identified in the specification. Secondly, chemically synthesized anti-mimotope having SEQ ID NO:94 inhibited ristocetin-induced aggregation (Specification page 45, lines 1-9). Further, the complementary structure is shown in Figures 12a-c.

Accordingly, the rejection of claims 9 and 11 for lack of enablement is improper and should be withdrawn.

C. Issue 3: Whether claim 11 is properly rejected under 35 U.S.C. § 112 (second paragraph) for indefiniteness where the claim, as written, is definite.

The amendment submitted to the U.S. Patent and Trademark Office on February 12, 2004 is believed to overcome this rejection.

For the above reasons, applicant maintains that the claims define patentable subject matter and accordingly the claims should be allowed.

Respectfully submitted,

February 17, 2004
Date

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I hereby certify that this document is being deposited with the U.S. Postal Service as first class mail on 2/17/04 under 37 CFR 1.8 and is addressed to the Commissioner for Patent, PO Box 1450, Alexandria, VA 22313-1450

Signature of Person Mailing Correspondence

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IX. Appendix

9. An isolated peptide of 5 to 20 or 20 to 40 amino acids residues in length capable of binding to a second peptide having an amino acid sequence as shown in SEQ ID NO:174, wherein the isolated peptide inhibits ristocetin induced aggregation of platelets, and wherein the isolated peptide has a three dimensional structure complementary to the three dimensional structure of the second peptide.

11. An isolated peptide of 5 to 20 or 20 to 40 amino acid residues in length which inhibits ristocetin induced aggregation of platelets, the isolated peptide being identified by:

selecting a library of test peptides, each test peptide being of 5 to 20 or 20 to 40 amino acid residues in length;

exposing the library of test peptides to a sample peptide consisting of an amino acid sequence as shown in SEQ ID NO:174;

selecting test peptides from the library that binds to the sample peptide;

screening the selected test peptides for ability to inhibit ristocetin induced aggregation of platelets; and

identifying the screened test peptides that inhibit ristocetin induced aggregation of platelets to isolate the peptide of 5 to 20 or 20 to 40 amino acid residues in length which inhibits ristocetin induced aggregation of platelets.